

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 23 FEB 2004

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Applicant's or agent's file reference J3677 (C) /RJG	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/EP 03/06991	International filing date (day/month/year) 30.06.2003	Priority date (day/month/year) 15.07.2002
International Patent Classification (IPC) or both national classification and IPC A61K7/06		
Applicant UNILEVER PLC et al.		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of sheets.

- This report contains indications relating to the following items:
 - ☒ Basis of the opinion
 - ☐ Priority
 - ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - ☐ Lack of unity of invention
 - ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - ☐ Certain documents cited
 - ☐ Certain defects in the international application
 - ☐ Certain observations on the international application

Date of submission of the demand 22.11.2003	Date of completion of this report 19.02.2004
Name and mailing address of the International preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Donovan-Beermann, T Telephone No. +49 89 2399-8213 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/EP 03/06991**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-30 as originally filed

Claims, Numbers

1-17 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 13

because:

☒ the said international application, or the said claims Nos. 13 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-17
	No: Claims	
Inventive step (IS)	Yes: Claims	1-17
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-12, 14-17
	No: Claims	

2. Citations and explanations

see separate sheet

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EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP03/06991

Ad Section III:

Claim 13 refers to a method falling under the provisions of Rule 67.1(iv). According to Art.34(4)(a)(i), this claim is therefore not assessed in regard to industrial applicability.

For the assessment of the present claim 13 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Ad Section V:

The present application relates to hair and/or scalp treatment compositions containing tulsi oil together with a metal pyrithione, capable of synergism.

The application relates also to the use of tulsi oil or components thereof and a synthetic antimicrobial agent, in the manufacture of a composition for the treatment/prevention of dandruff. Components of tulsi oil are eugenol, terpinen-4-ol, linalool or alpha-terpineol. The preferred antimicrobials are zinc pyrithione, climbazole, octopirox (piroctone omadine) and ketoconazole.

The following documents are cited in the present procedure:

- D1: DATABASE KOSMET[Online], Jadhav V A, "Antidandruff Herbal Cosmetceuticals - A Novel Approach" retrieved from STN Database accession no. 24660 & IFSCC Conference, May 7-9, 2001, Stockholm, Sweden, "Quality of Cosmetics; An explosive myth ?", p211-216.
- D2: WO 01 47481 A (DASCALU AVI ;ORON YORAM (IL); PHARMASKIN LTD (IL)) 5 July 2001 (2001-07-05)
- D3: US-B-6 323 1661 (KAMIYA AKIRA) 27 November 2001 (2001-11-27)
- D4: WO 87 06827 A (ROBERTET SA) 19 November 1987 (1987-11-19)
- D5: DATABASE CA [Online] CHEMICAL ABSTRACTS SERVICE, COLUMBUS,

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International application No. PCT/EP03/06991

OHIO, US; CHENG, JINXUE: 'Antiitching and antidandruff shampoo containing extracts of snake tissues and medicinal plants' retrieved from STN Database accession no. 131:9442 XP002219806 & CN 1 116 234 A (PEOP. REP. CHINA) 7 February 1996 (1996-02-07)

The use of Tulsi oil in the control of dandruff is known from D1, as is the use of certain of its component compounds against dandruff (see D3 and D4). The use of known antimicrobials such as zinc pyrithione or piroctone olamine in dandruff control is also known.

The use of combinations of Tulsi oil or components thereof with further antimicrobials in dandruff control is novel (Art.33(2) PCT). The applicant has shown synergistic effects for many combinations, thus inventive step can also be acknowledged (Art.33(3) PCT).

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 to D5 is not mentioned in the description, nor are these documents identified therein.